

# **FDA-AIChE Workshop on Adopting Continuous Manufacturing 2016**

Overcoming the Perceived Obstacles

Bethesda, Maryland, USA  
29 February - 2 March 2016

ISBN: 978-1-5108-2180-4

**Printed from e-media with permission by:**

Curran Associates, Inc.  
57 Morehouse Lane  
Red Hook, NY 12571



**Some format issues inherent in the e-media version may also appear in this print version.**

Copyright© (2016) by AIChE  
All rights reserved.

Printed by Curran Associates, Inc. (2016)

For permission requests, please contact AIChE  
at the address below.

AIChE  
120 Wall Street, FL 23  
New York, NY 10005-4020

Phone: (800) 242-4363  
Fax: (203) 775-5177

[www.aiche.org](http://www.aiche.org)

**Additional copies of this publication are available from:**

Curran Associates, Inc.  
57 Morehouse Lane  
Red Hook, NY 12571 USA  
Phone: 845-758-0400  
Fax: 845-758-2633  
Email: [curran@proceedings.com](mailto:curran@proceedings.com)  
Web: [www.proceedings.com](http://www.proceedings.com)

# TABLE OF CONTENTS

## **CONTINUOUS MANUFACTURING OF PHARMACEUTICALS – WHY AND WHY NOW?**

<b>Continuous Manufacturing: Achieving the Vision of Modernizing Pharmaceutical Manufacturing</b> .....	1
<i>R. Madurawe</i>	
<b>Approaches to Regulatory Engagement and Filing for Continuous Manufacturing</b> .....	15
<i>M. Buswell</i>	
<b>Design and Implementation of a Small Footprint Continuous API Facility for Portfolio Commercialization</b> .....	22
<i>E. McManus</i>	

## **TOP CHALLENGES FACED IN INDUSTRY BASED FOCUS GROUPS**

<b>Perceived Challenges with FDA/EU/Other Regulatory Review Questions, as well as PAIs</b> .....	37
<i>N/A</i>	
<b>AIChE FDA Workshop on Adopting Continuous Manufacturing &amp; Applicability of Continuous Manufacturing to a Diverse Pharmaceutical Portfolio</b> .....	43
<i>N/A</i>	
<b>Specific Skills Gaps</b> .....	48
<i>N/A</i>	
<b>Topic 4: Needed Equipment and Associated Facility Cost Group Demographics</b> .....	50
<i>N/A</i>	

## **PART 1: CONTINUOUS PROCESSING AND ENHANCED PROCESS CONTROL: THE REALIZATION OF QBD**

<b>How Process Models can Facilitate Quality Risk Management for Emerging Technologies</b> .....	60
<i>T. O'Connor</i>	
<b>Strategies to Accelerate Process Control Adoption in the Pharmaceutical Industry</b> .....	73
<i>R.D. Braatz</i>	
<b>An Integrated Multi-layer Approach to Control Strategy for Continuous Drug Product Manufacture</b> .....	82
<i>A. Almaya</i>	
<b>Control Strategy, Residence Time Distribution, and Real Time Release Implementation for Continuous Drug Product Manufacturing</b> .....	100
<i>S. Nielsen</i>	

## **PART 2: CONTINUOUS PROCESSING AND ENHANCED PROCESS CONTROL: THE REALIZATION OF QBD**

<b>A Decade's Experience Delivering Clinical and Commercial Supplies using Fully Continuous Hot Melt Extrusion</b> .....	115
<i>R. Meyer, C. Neu, B. Smith-Goettler</i>	
<b>Author Index</b>	